



6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2016-0109; FRL – 9971-51-OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Pesticide Data Call-in Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), “Pesticide Data Call-in Program” (EPA ICR No. 2288.03, OMB Control No. 2070-0174) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a reinstatement of a previously approved ICR. Public comments were previously requested via the *Federal Register* on August 23, 2017 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit your comments, referencing Docket ID Number EPA-HQ-OPP-2016-0109, to (1) EPA online using www.regulations.gov (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave., NW, Washington, DC 20460, and (2) OMB via email to oir_submission@omb.eop.gov.

Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Cameo Smoot, Field and External Affairs Division, (7596P), EPA, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (703) 305-5454; email address: smoot.cameo@epa.gov.

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's public docket, visit <http://www.epa.gov/dockets>.

Abstract: This ICR covers the information collection activities associated with the issuance of data-call-ins (DCIs) under section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In general, before manufacturers can sell pesticides in the United States, EPA must evaluate the pesticides thoroughly to ensure that they meet federal safety standards to protect human health and the environment. EPA grants a "registration" or license that permits a pesticide's distribution, sale, and use only after the company meets the scientific and regulatory requirements. In evaluating a pesticide registration application, EPA assesses a wide variety of potential human health and environmental effects associated with the use of the product. Applicants, or potential registrants, must generate or provide the scientific data necessary to address concerns pertaining to the identity, composition, potential adverse effects,

and environmental fate of each pesticide. The data allow EPA to evaluate whether a pesticide has the potential to cause harmful effects on certain non-target organisms and endangered species that include: humans; wildlife; plants; and surface water or ground water.

Through a rigorous scientific and public process, EPA specifies the kinds of data and information necessary to make regulatory judgments about the risks and benefits of pesticide products under FIFRA sections 3, 4 and 5, as well as the data and information needed to determine the safety of pesticide chemical residues under FFDCA section 408. The regulations in 40 CFR part 158 describe the minimum data and information EPA typically requires to support an application for pesticide registration or amendment; support the reregistration of a pesticide product; support the maintenance of a pesticide registration by means of the data call-in process; or establish or maintain a tolerance or exemption from the requirements of a tolerance for a pesticide chemical residue. As described in 40 CFR 158.30, however, FIFRA provides EPA with flexibility to require, or not require, data and information for the purposes of making regulatory judgments for individual pesticide products, thereby allowing for the data required to be modified on an individual basis to fully characterize the use and properties, characteristics, or effects of specific pesticide products under review. The Agency encourages each applicant to consult with EPA to discuss the data requirements prior to and during the registration process. In addition, the Agency cautions applicants that the data routinely required by the regulations may not be sufficient to permit EPA to evaluate the potential of the product to cause unreasonable adverse effects on man or the environment. EPA may, therefore, require the submission of additional data or information beyond that specified in the regulations if such data or information are needed to evaluate a pesticide product as required by FIFRA and FFDCA.

EPA uses the DCIs issued to acquire the data that has been deemed necessary for the

Agency's statutorily mandated review of a pesticide's registration, which require it to assess whether the continued registration of an existing pesticide causes an unreasonable adverse effect on human health or the environment and whether the Agency will pursue regulatory measures.

Respondents/affected entities: Pesticide registrants - North American Industrial Classification System (NAICS) code 325320 (Pesticide and Other Agricultural Chemical Manufacturing).

Respondent's obligation to respond: Mandatory under FIFRA section 3(c)(2)(B).

Estimated number of respondents: 122 (total).

Frequency of response: On occasion.

Total estimated burden: 615,447 hours (per year). Burden is defined at 5 CFR 1320.03(b)

Total estimated cost: \$ 43,792,523 (per year). There are no capital investment or maintenance and operational costs associated with this collection.

Changes in the Estimates: There is an increase of 353,146 hours in the total estimated respondent burden compared with that identified in the last ICR approved by OMB. The burden increase is a cumulative result of the program implementing new methodologies to calculate respondent burden, the inclusion of a new information collection group – consortium participants – to more accurately reflect the respondent burden, renaming and recalculating an existing information collection group from Enforcement and Unanticipated Incident activities to Maintenance DCIs, and the acceleration of the Registration Review Program. All of these activities have contributed to the significant increase in number of DCIs to be issued (221 versus 45) annually.

Courtney Kerwin,
Director,

Regulatory Support Division.

[FR Doc. 2018-01269 Filed: 1/23/2018 8:45 am; Publication Date: 1/24/2018]